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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/652,138 | 08/29/2003 | Koichiro Tanaka | 8375-006/DVA | 1171 |
| 27572 | 7590 | 09/11/2006 | EXAMINER | |
| HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303 | | | | FAY, ZOHREH A |
| ART UNIT | | PAPER NUMBER | | |
| | | 1618 | | |

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|---------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/652,138 | TANAKA, KOICHIRO |
| | Examiner Zohreh A. Fay | Art Unit 1618 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 7-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 7-22 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.

- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: ____.

Claims 7-18 are presented for examination.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-9, 11-13 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Viegas et al. (U.S. Patent 5,587,175). Viegas et al. teach the use of hyaluronic acid, chondroitin sulfate and hydroxypropyl methyl cellulose in combination with active ingredients such as anti-microbial and anti-inflammatory agents in an ophthalmic formulation for protection of cornea, which can be used in the body cavity or by injection. See the abstract, column 4, lines 56-60, column 6, lines 48-65 and examples of 1, 2 and 5.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10, 14, 15 and 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Viegas et al. (U.S. Patent 5,587,175) in view of Chang (U.S. Patent 6,051,560).

Viegas et al. teach the use of the claimed viscoelastic agents, hyaluronic acid, chondroitin sulfate and hydroxymethyl cellulose in combination with the claimed active ingredients, such as anti-microbials and anti-inflammatory agents for protection of cornea during surgery or trauma. See the abstract, column 4, lines 56-60, column 6, lines 48-65 and examples 1, 2 and 5. The primary reference differs from the claimed invention in the use of the combination of hyaluronic acid and chondroitin sulfate and also preservation against the infection of internal ocular space in a surgical operation. Chang et al. teach that the combination of hyaluronates and chondroitin sulfate has been used to protect cell layers and tissues subject to trauma during ocular surgery such as lens implantation, corneal transplantation and other intraocular surgical

operations. See column 1, lines 30-35 and claims 1-14. It would have been obvious to a person skilled in the art to combine hyaluronic acid and chondroitin sulfate and use it for protecting tissues during ophthalmic surgery, considering that Chang et al. teach the use of such combination in ophthalmic surgery as old. It would have also been obvious to use the claimed combination for preserving against ocular infection, considering that preserving against infection is an inherent property of anti-microbial agents.

One skilled in the art would have been motivated to combine the teachings of the above references, since one relates to the use of the claimed viscoelastic agents, such as hyaluronates, chondroitin sulfate and hydroxylmethyl cellulose individually in combination with the claimed anti-microbial and anti-inflammatory agents for protecting cells during ophthalmic surgery and trauma, and the other relates to the use of the combination of hyaluronates and chondroitin sulfate in the intraocular surgery as old. The preservation of ocular space by the addition of anti-microbial agent is the inherent property of such agents. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 10, 14, 15 and 17-22 are properly rejected under 35 U.S.C. 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh A. Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Z.F

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1200

